



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**42 CFR Part 88**

**World Trade Center Health Program; Petition 003--Kidney Damage;  
Finding of Insufficient Evidence**

**AGENCY:** Centers for Disease Control and Prevention, HHS.

**ACTION:** Denial of petition for addition of a health condition.

-----

**SUMMARY:** On January 22, 2014, the Administrator of the World Trade Center (WTC) Health Program received a petition to add "kidney damage" (Petition 003) to the List of WTC-Related Health Conditions (List). The Administrator has not found sufficient scientific evidence to conduct an analysis of whether to add kidney damage and/or disease to the List. Accordingly, the Administrator finds that insufficient evidence exists to request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee (STAC), to publish a proposed rule, or to publish a determination not to publish a proposed rule.

**DATES:** The Administrator of the WTC Health Program is denying this petition for the addition of a health condition as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]

**FOR FURTHER INFORMATION CONTACT:** Rachel Weiss, Program Analyst, 4674 Columbia Parkway, MS: C-46, Cincinnati, OH 45226; telephone (855)818-1629 (this is a toll-free number); email [NIOSHregs@cdc.gov](mailto:NIOSHregs@cdc.gov).

## **SUPPLEMENTARY INFORMATION:**

### A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111-347), amended the Public Health Service Act (PHS Act) to add Title XXXIII<sup>1</sup> establishing the WTC Health Program within the Department of Health and Human Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers (responders) who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania, and to eligible persons (survivors) who were present in the dust or dust cloud on September 11, 2001 or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area.

All references to the Administrator of the WTC Health Program (Administrator) in this notice mean the Director of the National Institute for Occupational Safety and Health (NIOSH) or his or her designee.

Pursuant to § 3312(a)(6)(B) of the PHS Act, interested parties may petition the Administrator to add a health condition to the List

---

<sup>1</sup> Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm-61. Those portions of the Zadroga Act found in Titles II and III of Public Law 111-347 do not pertain to the WTC Health Program and are codified elsewhere.

in 42 CFR 88.1. Within 60 calendar days after receipt of a petition to add a condition to the List, the Administrator must take one of the following four actions described in § 3312(a)(6)(B) and 42 CFR 88.17: (i) request a recommendation of the STAC; (ii) publish a proposed rule in the **Federal Register** to add such health condition; (iii) publish in the **Federal Register** the Administrator's determination not to publish such a proposed rule and the basis for such determination; or (iv) publish in the **Federal Register** a determination that insufficient evidence exists to take action under (i) through (iii) above.

#### B. Petition 003

On January 22, 2014, the Administrator received a petition to add "kidney damage" to the List (Petition 003).<sup>2</sup> The petition was submitted by a Fire Department of New York (FDNY) firefighter who worked at Ground Zero in the aftermath of the September 11, 2001, terrorist attacks. The petitioner indicated that he had been diagnosed with kidney failure and shared a letter from his nephrologist explaining that he has "chronic kidney disease with unknown oetiology [sic]." Also included in his petition was a press release issued by the WTC-CHEST Program at Icahn School of Medicine at Mount Sinai (Mount Sinai) describing a forthcoming study by Mary Ann McLaughlin and others, finding a "significant link between a high level of exposure to particulate matter by first responders at Ground

---

<sup>2</sup> See Petition 003. WTC Health Program: Petitions Received. <http://www.cdc.gov/wtc/received.html>.

Zero and the increased level of the protein albumin in their urine.”<sup>3</sup>  
The anticipated study findings are described in an abstract  
supplement to the Journal of the American Society of Nephrology.<sup>4</sup>

### C. Administrator’s Determination on Petition 003

The Administrator has established a methodology for evaluating whether to add non-cancer health conditions to the List of WTC-Related Health Conditions.<sup>5</sup> A health condition may be added to the List if published, peer-reviewed epidemiologic evidence provides substantial support for a causal relationship between 9/11 exposures and the health condition in 9/11-exposed populations.<sup>6</sup> If the epidemiologic evidence provides modest support for a causal relationship between 9/11 exposures and the health condition, the Administrator may then evaluate studies of associations between the health condition and 9/11 agents.<sup>7</sup> If that additional assessment establishes substantial support for a causal relationship between a 9/11 agent or agents and the health condition, the health condition may be added to the List.

---

<sup>3</sup> Mount Sinai Hospital [November 9, 2013]. Kidney Damage in First Responders Linked to September 11. <http://www.mountsinai.org/about-us/newsroom/press-releases/kidney-damage-in-first-responders-linked-to-september-11>.

<sup>4</sup> McLaughlin MA, Sanghavi S, Maceda C, Woodward M, Crowley LE, Wyatt CM [2013]. New Evidence that Particulate Matter Exposure at Ground Zero is Associated with Kidney Damage.” J Am Soc Nephrol 24:663A. See <http://www.asn-online.org/education/kidneyweek/archives/>.

<sup>5</sup> This methodology, “Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions,” is available on the WTC Health Program website, at <http://www.cdc.gov/wtc/policies.html>.

<sup>6</sup> The substantial evidence standard is met when the Program assesses all of the available, relevant information and determines with high confidence that the evidence supports its findings regarding a causal association between the 9/11 exposure(s) and the health condition.

<sup>7</sup> The modest evidence standard is met when the Program assesses all of the available, relevant information and determines with moderate confidence that the evidence supports its findings regarding a causal association between the 9/11 exposure(s) and the health condition.

In accordance with § 3312(a)(6)(B) of the PHS Act and 42 CFR 88.17, described above, the Administrator has reviewed the evidence presented in Petition 003. The Administrator has also conducted a search of the existing scientific/medical literature for evidence that could establish a causal relationship between 9/11 exposure and kidney damage/disease. He did not find any peer-reviewed, published epidemiologic studies of 9/11-exposed populations supporting such an relationship. While the information reported in the McLaughlin et al. abstract is an important first step in scientific inquiry, the Administrator finds that an abstract is insufficient to serve as the scientific basis for adding an entire class of health conditions -- chronic kidney damage/disease -- to the List.

Because the McLaughlin et al. abstract is found to be insufficient to scientifically support the further consideration of kidney damage/disease and because it is clear to the Administrator that the scientific literature on 9/11 exposed-populations does not support a causal relationship between that exposure and kidney damage/disease, the Administrator has determined that requesting a recommendation from the STAC (pursuant to PHS Act, § 3312(a)(6)(B)(i) and 42 CFR 88.17(a)(2)(i)) is unwarranted. In prior actions, the Administrator requested a recommendation from the STAC when he determined that it would assist his evaluation; such as when, for example, the Administrator is in need of an interpretation of conflicting or inconclusive published scientific evidence.

Similarly, the Administrator has determined that insufficient evidence exists to take further action, including either proposing the addition of kidney damage/disease to the List (pursuant to PHS Act, § 3312(a)(6)(B)(ii) and 42 CFR 88.17(a)(2)(ii)) or publishing a determination not to publish a proposed rule in the **Federal Register** (pursuant to PHS Act, § 3312(a)(6)(B)(iii) and 42 CFR 88.17(a)(2)(iii)). In order to publish such a proposed addition or a determination not to propose a rule, the Administrator would first need to find that enough scientific evidence is available to analyze whether 9/11 exposures are associated with the health condition. Since the Administrator is unable to identify sufficient evidence to conduct an analysis of whether to add the health condition, the Administrator (pursuant to PHS Act, § 3312(a)(6)(B)(iv) and 42 CFR 88.17(a)(2)(iv)) is publishing a determination that he cannot take any of the other statutory and regulatory actions.

For the reasons discussed above, the request made in Petition 003 to add kidney damage/disease to the List of WTC-Related Health Conditions is denied.

Dated: March 24, 2014

---

John Howard, M.D.

Administrator, World Trade  
Center Health Program and

Director, National Institute  
for Occupational Safety and  
Health, Centers for Disease  
Control and Prevention,  
Department of Health and  
Human Services

[FR Doc. 2014-06906 Filed 03/28/2014 at 8:45 am; Publication Date:  
03/31/2014]